PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
R. Sanders WILLIAMS *et al.*

Serial No.: 09/782,953

Filed: February 13, 2001

For: METHODS AND COMPOSITIONS RELATING TO MUSCLE SELECTIVE CALCINEURIN INTERACTING PROTEIN (MCIP)

Group Art Unit: 1653

Examiner: Liu, Samuel W.

Atty. Dkt. No.: MYOG:036US/SLH

CERTIFICATE OF MAILING
37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Appeal Brief, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-01450 on the date below:

September 20, 2005
Date

Steven L. Highlander

APPEAL BRIEF

09/23/2005 AKELECH1 00000020 09872953
01 FC:2402 250.00 OP

25578308.1

TABLE OF CONTENTS

Page

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: R. Sanders WILLIAMS *et al.*	Group Art Unit: 1653
Serial No.: 09/782,953	Examiner: Liu, Samuel W.
Filed: February 13, 2001	Atty. Dkt. No.: MYOG:036US/SLH
For: METHODS AND COMPOSITIONS RELATING TO MUSCLE SELECTIVE CALCINEURIN INTERACTING PROTEIN (MCIP)	

APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-01450

Dear Sir:

This brief is filed (in triplicate) in response to the Final Office Action mailed on April 20, 2005, regarding the above-captioned application. This brief is due on September 22, 2005, by virtue of the Notice of Appeal received by the PTO July 22, 2005. The fees for the brief are enclosed; however, should any other fees be due, or should appellants' check be missing, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.:50-1212/MYOG:036US/SLH. Please date stamp and return the attached postcard as evidence of receipt.

I. Status of the Claims

Claims 1-101 were filed with the application. Claims 1-58, 60, 63-69 and 71-101 have been canceled. Thus, claims 59, 61, 62, and 70 are pending, stand rejected, and are appealed. A copy of the pending claims is attached.

II. Status of the Amendments

An amendment was filed with appellants' Notice of Appeal, the entry of which was denied in Advisory Actions dated March 18, 2004 and June 2, 2004. While the non-entry of these amendments is not an appealable issue, appellants nonetheless feel compelled to point out that the improper grounds for non-entry. The reasoning for non-entry of the amendments after final is said to reside, at least in part, that the term "selecting" is "new matter." Advisory Action of June 2, 2004, page 2, first ¶. However, ***the recitation of selecting was entered into the claims on November 12, 2003, in response to a non-final action***. Thus, this ***cannot*** be grounds for non-entry of the after-final amendment.

III. Statement of Interest

The real party in interest is the assignee, The Board of Regents, University of Texas System.

IV. Related Appeals and Interferences

There are no related appeals or interferences.

V. Summary of the Invention

The present invention is drawn to methods of modulating muscle cell growth comprising (a) providing a modulator of MCIP expression; and (b) administering a modulator to a subject,

whereby administration of said modulator results in modulation of muscle cell growth. Specification at page 6, lines 24-27, and page 7, lines 1-13.

VI. Issues on Appeal

Are claims 59, 61, 62 and 70 indefinite under 35 U.S.C. §112, second paragraph?

Do claims 59 and 70 introduce "new matter" such that contravene the requirements of 35 U.S.C. §112, first paragraph?

VII. Grouping of the Claims

The claims stand or fall together.

VIII. Summary of the Argument

The rejections under §112, second paragraph, are based on the premise that a generic claims that covers both up- and down-regulation of muscle cell growth are indefinite. This is not the case. The claims clearly set for that an agent is provided to a subject, and that that agent may either increase (agonist) or decrease (antagonist) the growth of muscle cells in the subject. Whatever other issues might be raised by these claims, clarity cannot reasonably be challenged. Moreover, the use of the term "second pharmaceutical composition" in claim 70 is not indefinite, and in any event, appellants have offered an amendment to claim 59 that would resolve the issue.

The new matter rejections are both improper because the specification, though not providing precisely identical wording for the terms "selecting" and "human subject," clearly set forth these embodiments. Moreover, the law provides that the specification need no provide literal support for claim amendments so long as they are reasonably apparent to one of ordinary skill in the art.

IX. Argument

A. Standard of Review

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act, 5 U.S.C. §706(A), (E), 1994. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). Moreover, the Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). In *In re Gartside*, the Federal Circuit stated that "the 'substantial evidence' standard asks whether a reasonable fact finder could have arrived at the agency's decision." *Id.* at 1312. Accordingly, it necessarily follows that an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences.

B. Rejection Under 35 U.S.C. §112, Second Paragraph

The examiner has rejected claims 59, 61, 62 and 70 under the second paragraph of §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter. The examiner continues to argue that the claims are indefinite in the use of the term "modulation" as not defining whether the regulation is up or down. This objection clearly is improper, as explained in detail below.

The very essence of the present claims is to identify molecules that may modify MCIP expression ***in either direction – up or down***; hence the use of the word ***modulation***, which is generic to up- or down-regulation, accurately reflects the intent of the claim, and is thus very much correct in its usage. There is nothing indefinite about this recitation, and reversal of this rejection is respectfully requested.

In the most recent Advisory Action, the examiner attempts to refine his reasoning by arguing that a modulator cannot be both an agonist and an antagonist, and hence these recitations in claims 61 and 62, respectfully, are also unclear. Nothing could be further from the truth. Claims 61 and 62 are dependent claims. Thus, they further limit the subject matter of claim 59, which as already pointed out, is generic with respect to the direction of regulation. There is absolutely nothing indefinite about these claims either. Reversal of this rejection is respectfully requested as well.

Claim 70 is also rejected over the term "second pharmaceutical agent." Appellants previously amended claim 70 to clarify that the second pharmaceutical agent is distinct from the agent provided in claim 59. Appellants attempted to amend claim 59 to specify a first pharmaceutical agent (*i.e.*, the modulator), in that claim, but entry of this amendment was denied. Appellants are more than willing to provide an additional amendment, or authorize the examiner to make such an amendment. Even if this amendment is not entered, however, appellants submit that one of skill in the art would recognize that the "second pharmaceutical agent" of claim 70 is in addition to the modulator of claim 59, and thus there is no issue of indefiniteness. Reversal of this rejection is respectfully requested.

C. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 59 and 70 are newly rejected under the first paragraph of §112 as introducing new matter into the claims. The alleged new matter is the inclusion of the terms "selecting" and "human subject" in claim 59, and "human subject" in claim 70. Appellants traverse.

In order for amended claims to meet the written description requirements of §112, first paragraph, the description must "reasonably [convey] to the artisan that the inventor had possession at that time of the later claimed subject matter." *TurboCare Div. Demag Delaval*

Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111, 1118, 60 U.S.P.Q.2d 1017, 1022 (Fed. Cir. 2001). An amendment by itself does not constitute new matter "unless it discloses an 'invention, process, or apparatus not theretofore described.'" *Triax Co. v. Hartman Metal Fabricators, Inc.*, 479 F.2d 951, 956-957, 178 U.S.P.Q. 142, 146 (2d Cir. 1973). If an amendment is made merely to render explicit what had been implicitly disclosed originally, the fact that new language is added does not make the new language *ipso facto* new matter. *In re Wright*, 343 F.2d 761, 767, 145 U.S.P.Q. 182, 188 (CCPA 1965).

Therefore, the fundamental inquiry is whether the original application supports the amended matter. *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352, 55 U.S.P.Q.2d 1650, 1653 (Fed. Cir. 2000). The specification "need not describe the claimed subject matter in exactly the same terms as used in the claims" in order to comply with the written description requirement. *All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 309 F.3d 774, 779, 64 U.S.P.Q.2d 1945, 1948 (Fed. Cir. 2002). Furthermore, "the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize . . . that the new language reflects what . . . has been invented." *Id.*

Appellants once again submit that the inclusion of the term "human subject" in claims 59 and 70 in no way constitutes new matter, as the use of this term is clearly supported by the specification. For example, page 17, line 4 of the specification states, "[c]urrent results indicate that the interaction between MCIP and calcineurin is pertinent to the pathobiology, and ultimately to the therapy, of ***human disease***." Emphasis added. Page 34, line 19 of the specification states, "[a]ntisense RNA constructs, or DNA encoding such antisense RNA's, may be employed to inhibit gene transcription or translation or both within a host cell, either *in vitro*

or *in vivo*, such as within a host animal, including a ***human subject***." Emphasis added. These statements unequivocally support the use of the invention in a human subject.

Regardless, the specification need not even use the same language as in the claims as long as one skilled in the art would understand that the applicant had invented what is claimed. *All Dental Prodx*, 309 F.3d at 779, 64 U.S.P.Q.2d at 1948. An entire section beginning at page 68, line 19 of the specification, is devoted to the administration to ***patients***. The last sentence of this section states that, "for ***human*** administration, preparation should meet sterility, pyrogenicity, general safety and purity standards as required by the FDA Office of Biologics standards" making it abundantly clear that the term patients is synonymous with human subjects. In this context, one skilled in the art would easily understand "patients" to be human subjects rather than animal subjects. Thus, in light of the specification, the use of the term "human subject" does not constitute new matter under §112, first paragraph.

Appellants also disagree that the term "selecting" is, in any way, new matter. Pages 67, lines 1-10, discuss four possible agents that may be chosen to modulate MCIP function and states "[modulation] may be accomplished in ***one*** of several ways." Emphasis added. The claim calls for giving the patient "***a*** modulator of MCIP expression" as in the singular sense. One skilled in the art would understand that a physician or health care provider would have to choose one of the modulators, *i.e.*, ***select*** a modulator, rather than give the patient all the possible compounds. Furthermore, the specification discloses use of a modulator in combination with another pharmaceutical agent on page 67. The specification describes situations where "the other agent and expression construct are applied separately." Significantly, the term "expression construct" is expressed in a singular sense. Page 68, line 7 states, "it is also conceivable that more than one administration of ***either*** a MCIP-1 or MCIP-2 gene ... will be desired." Emphasis added.

Therefore, one of the MCIP modulators is selected and administered rather than both of the possible modulators.

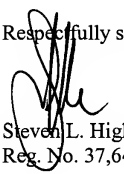
As stated before, the specification need not specifically mention a limitation as long as one skilled in the art would recognize what has been invented. *All Dental Prodx*, 309 F.3d at 779, 64 U.S.P.Q.2d at 1948. Plainly, one skilled in the art would implicitly construe these statements as selecting one type of MCIP modulator.

Thus, as should be evident from the foregoing discussion, neither of the questioned terms constitutes new matter under 35 U.S.C. §112, first paragraph. Reversal of the rejection is respectfully requested.

X. Conclusion

In light of the foregoing, appellants respectfully submit that all pending claims are definite and supported by the application as filed. Therefore, it is respectfully requested that the Board reverse each of the pending rejections.

Respectfully submitted,



Steven L. Highlander
Reg. No. 37,642

Fulbright & Jaworski L.L.P.
600 Congress Ave., Suite 2400
Austin TX 78701
512-474-5201

Date: September 20, 2005

APPENDIX OF CLAIMS

1-58. (Canceled)

59. (Previously presented) A method of modulating muscle cell growth in a human subject comprising:

(a) identifying a human subject in need of muscle cell growth modulation;
(b) selecting a small molecule modulator of MCIP1 expression; and
(b) administering said modulator to said human subject,

whereby administration of said modulator results in modulation of muscle cell growth in said subject.

60. (Canceled)

61. (Previously presented) The method of claim 59, wherein said small molecule modulator is an agonist of muscle cell growth.

62. (Previously presented) The method of claim 59, wherein said small molecule is an antagonist of muscle cell growth.

63-69. (Canceled)

70. (Previously presented) The method of claim 59, further comprising administering to said human subject a second pharmaceutical agent used to treat cardiac disease.

71-101. (Canceled)

CITED AUTHORITIES

Administrative Procedure Act, 5 U.S.C. §706(A), (E), 1994

All Dental Prodx, LLC v. Advantage Dental Products, Inc., 309 F.3d 774, 779, 64 U.S.P.Q.2d 1945, 1948 (Fed. Cir. 2002)

Dickinson v. Zurko, 527 U.S. 150, 158 (1999)

In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000)

In re Wright, 343 F.2d 761, 767, 145 U.S.P.Q. 182, 188 (CCPA 1965)

Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352, 55 U.S.P.Q.2d 1650, 1653 (Fed. Cir. 2000)

Triax Co. v. Hartman Metal Fabricators, Inc., 479 F.2d 951, 956-957, 178 U.S.P.Q. 142, 146 (2d Cir. 1973)

TurboCare Div. Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111, 1118, 60 U.S.P.Q.2d 1017, 1022 (Fed. Cir. 2001)

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None